PATENT
Attorney Docket No. 015-C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
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DAVID H. COLE	)	Examiner: Unassigned
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Application No.: Unassigned	)	Art Unit: Unassigned
	)	
Filed: Herewith	)	
	)	
For: METHODS AND DEVICES USING MAGNETIC FORCE TO FORM AN ANASTOMOSIS BETWEEN HOLLOW BODIES	)	**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, please amend the subject application as indicated below.

IN THE SPECIFICATION:

Please insert the following header and paragraph after the title and before "BACKGROUND OF THE INVENTION"

-- CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of application Serial No. 09/562,599, filed April 29, 2000. The complete disclosure of the aforementioned related U.S. patent application is hereby incorporated herein by reference for all purposes.--

Please replace the first paragraph with the following corrected paragraph:

--The invention relates to methods and devices for forming an anastomosis between two hollow bodies, and more particularly to forming an anastomosis using magnetic force.--

Please replace the first paragraph on page 3 with the following corrected paragraph:

-- According to one embodiment, the invention provides a method using magnetism for forming an anastomosis between first and second hollow bodies. Each hollow body has a lumen and an opening extending into the lumen. The method is carried out by positioning a first securing component adjacent the opening in the first hollow body, positioning a second securing component adjacent the opening in the second hollow body, and using magnetic force to form an anastomosis between the first and second hollow bodies with the lumens of the first and second hollow bodies in communication.--

Please replace the paragraph beginning on page 3, line 10 with the following corrected paragraph:

--According to another embodiment, the invention provides a method using magnetism for forming an anastomosis between first and second hollow bodies, each of which has a lumen. The method uses magnetic force to form an anastomosis between first and second hollow bodies so as to place their lumens in communication. The first hollow body has proximal and distal portions between which the anastomosis is disposed.--

Please replace the paragraph beginning on page 4, line 11 with the following corrected paragraph:

--According to yet another embodiment, the invention provides a system for forming an anastomosis between first and second hollow bodies in a patient's body. The system includes first and second securing components capable of producing a magnetic field that applies force to maintain the securing components in a desired relative position. The first securing component has an opening and is substantially plate-shaped and sized and configured to be at least partially received in a lumen of a hollow body in a patient's body, and the second component has an opening and is sized and configured to be positioned adjacent a second hollow

body in the patient's body for forming an anastomosis between the first and second hollow bodies.--

Please replace the paragraph beginning on page 4, line 24 with the following corrected paragraph:

--Fig. 6 is a perspective view showing two hollow bodies adapted to be joined in communication via an end-to-side anastomosis;--

Please replace the paragraph beginning on page 4, line 26 with the following corrected paragraph:

--Fig. 7 is a perspective view showing two hollow bodies adapted to be joined in communication via a side-to-side anastomosis;--

Please replace the paragraph beginning on page 4, line 28 with the following corrected paragraph:

--Fig. 8 is a perspective view showing two hollow bodies adapted to be joined in communication via an end-to-end anastomosis;--

Please replace the paragraph beginning on page 5, line 4 with the following corrected paragraph:

--Fig. 9A is a sectional view of the anastomosis shown in Fig. 9;--

Please replace the paragraph beginning on page 6, line 10 with the following corrected paragraph:

-- Fig. 18B is a longitudinal sectional view of the hollow body and securing component shown in Fig. 18A;--

Please replace the heading on page 7, line 14 with the following corrected heading:

--DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS--

Please replace the paragraph beginning on page 7, line 15 with the following corrected paragraph:

--The present invention relates to methods and devices for forming an anastomosis between first and second (or additional) hollow bodies located in a patient's body, for example, a connection between a graft vessel and coronary or peripheral blood vessels, viscera, reproductive ducts, etc. The anastomosis places the hollow bodies, more specifically the lumens of the hollow bodies, in communication. In the case of blood-carrying bodies (or other hollow bodies that carry fluid) the anastomosis places the bodies in fluid communication . The hollow bodies being joined may comprise native or autologous vessels, vessels formed of synthetic material such as ePTFE, DACRON®, etc.--

Please replace the paragraph beginning on page 8, line 3 with the following corrected paragraph:

--Fig. 2 shows an elliptical-shaped, anastomotic securing component 14 with an opening 16. The securing component 14 is generally plate-shaped and the opening 16 is configured to provide the securing component 14 with larger end portions 18 than side portions 20. Fig. 3 shows a racetrack-shaped securing component 22 with an opening 24. As in securing component 14, the opening 24 provides securing component 22 with larger end portions 26 than side portions 28. Fig. 4 shows a securing component 30 with an opening 32, two end portions 34, 36 and two side portions 38. The securing component 30 has a generally racetrack-shaped configuration, however, the end portion 36 is larger than the end portion 34 which provides the component 30 with an asymmetric configuration. Stated otherwise, the opening 32 is not centrally located with respect to the body of the component 30, unlike the openings 12, 16 and 24 of respective securing components 10, 14 and 22 shown in Figs. 1-3. Also, the end 36 provides a tapered leading edge for easier introduction into a hollow body such as a blood vessel.--

Please replace the paragraph beginning on page 3, line 15 with the following corrected paragraph:

-- According to another embodiment, the invention provides a method using magnetism for forming an anastomosis between first and second hollow bodies with lumens and openings extending into the lumens. This method is performed by positioning a first securing component adjacent an opening in the first hollow body, positioning a second securing component adjacent an opening in the second hollow body, and using magnetic force to form an

anastomosis between the first and second hollow bodies with the lumens of the first and second hollow structures in communication. At least one of the securing components is positioned without everting the hollow body.--

Please replace the paragraph beginning on page 3, line 23 with the following corrected paragraph:

-- According to still another embodiment, the invention provides a method using magnetism for forming an anastomosis between first and second hollow bodies by positioning a first securing component adjacent the first hollow body, positioning a second securing component adjacent the second hollow body, and using magnetic force to control the relative position of the first and second securing components and to form an anastomosis between the first and second hollow bodies. The blood-carrying lumens of the first and second hollow bodies are placed in communication, with at least one of the first and second securing components at least partially disposed within the blood-carrying lumen of one of the first and second hollow bodies.--

Please replace the paragraph beginning on page 9, line 6 with the following corrected paragraph:

--According to preferred embodiments of the invention the anastomotic securing components are formed of or have incorporated therein a material capable of producing a magnetic field that acts to maintain the components in a desired positional relationship. The magnetic field results in the securing components maintaining the first and second hollow bodies in a desired position so as to be in fluid-tight communication. The material used to form one or both securing components is preferably magnetic, ferromagnetic or electromagnetic.--

Please replace the paragraph beginning on page 9, line 27 with the following corrected paragraph:

--Suitable materials that may be used to form an anastomotic securing component that is capable of producing a magnetic field include NdFeB (Neodymium Iron Boron), SmCo (Samarium Cobalt), and Alnico (Aluminum Nickel Cobalt). NdFeB is currently preferred for its force characteristics. The amount of force exerted will depend on various factors including the

materials used, the size of the magnets and the number of magnets. In addition, different applications will call for different force ranges. For instance, it may be desirable to minimize the force as much as possible while still achieving a fluid-tight and secure attachment when treating small diameter blood vessels. As an example, in anastomosing coronary vessels, it is preferred to use anastomotic securing components that produce magnetic force in the area of less than 0.25 lbs, and more preferably approximately 0.15 lbs or less.--

Please replace the paragraph beginning on page 10, line 7 with the following corrected paragraph:

--Figs. 6-8 depict first and second hollow bodies that have been prepared for anastomosis in three different manners. Fig. 6 shows a first hollow body 50 with an opening 52 that is adapted to be joined to an opening 54 of a second hollow body 56 to form an end-to-side anastomosis. The completed anastomosis places the lumens of the respective hollow bodies in communication . The opening 52 is formed in the wall of the first hollow body 50, for example, by incising or punching the tissue of the wall, while the opening 54 is defined by an end of the second hollow body 56. Fig. 7 shows a first hollow body 58 with an opening 60 adapted to be joined to an opening 62 of a second hollow body 64, thereby forming a side-to-side anastomosis that places their lumens in communication. The openings 60, 62 are formed in the walls of the hollow bodies 58, 64, for example, as described above regarding opening 52. Fig. 8 shows a first hollow body 66 with an opening 68 adapted to be joined to an opening 70 of a second hollow body 72 to form an end-to-end anastomosis. Each opening 68, 70 is defined by an end of its associated hollow body 66, 72.--

Please replace the paragraph beginning on page 11, line 9 with the following corrected paragraph:

--One exemplary application of this particular feature of the invention comprises a securing component with a middle layer of NdFeB (Neodymium Iron Boron -- magnetic) and two outer layers of 302 stainless steel (non-magnetic). The outer layers are bonded by suitable adhesive to the middle layer. Alternatively, the two outer layers could comprise a magnetic material, e.g., 440C stainless steel, surrounding a middle layer that is either magnetic or non-magnetic. As an example, the securing component may comprise a 0.008 inch thick magnetic

layer and two 0.001 inch outer steel layers. It will be understood that this aspect of the invention may be practiced using other materials.---

Please replace the paragraph beginning on page 11, line 17 with the following corrected paragraph:

--A benefit of this construction is that it allows the thickness of the magnetic layer to be reduced (which makes the brittle magnet more easily fractured) because the other layer(s) may be formed of a material which provide the assembly with the necessary strength, even if the other layer is very thin. In the above example, the steel layers may be very thin yet still able to absorb the load, e.g., the tensile forces that arise during movement of the hollow body or adjacent tissue. The particular overall dimensions of the securing component, as well as the dimensions of individual layer (or layers if a multilayer construction is used) will of course depend on the application. (As examples, for the securing component 22 shown in Fig. 3, the thickness in inches is preferably less than 0.040, and more preferably less than 0.020, e.g., approximately 0.015 or even less, e.g., 0.008.)--

Please replace the paragraph beginning on page 12, line 27 with the following corrected paragraph:

--Fig. 10D shows an embodiment of the invention similar to that of Fig. 10C with first and second securing components 112, 114 coupled to first and second hollow bodies 116, 118. The means for attaching the first securing component 112 to the first hollow body 116 in this embodiment comprises an expandable member 120, such as a stent, disposed within the lumen of the first hollow body. The member 120 forces the end of the first hollow body 116 against the first securing component 112 to attach the elements in a fluid-tight fashion. It will be appreciated that the embodiments of Figs. 10C and 10D are only two of the various ways in which a securing component may be coupled to a hollow body without everting tissue of the hollow body.--

Please replace the paragraph beginning on page 13, line 26 with the following corrected paragraph:

--Figs. 12 and 14A-14B show other embodiments of the invention wherein first and second hollow bodies 134, 136 are respectively provided with securing components in order to create a side-to-side anastomosis. The embodiment of Fig. 12 utilizes first and second securing components 138, 140 respectively positioned adjacent openings in the hollow bodies 134, 136. Each securing component 134, 136 includes a single member that may comprise one or more materials and one or more layers, as described above. The components may be fixed by adhesive or other means or remain in position via magnetic force, as explained above. The securing components 138, 140 are positioned through openings formed in the wall of the hollow bodies 134, 136 and are located within the respective lumens L1, L2 thereof, as shown in Figs. 14A and 14B. Once joined, the components 138, 140 form a fluid-tight anastomosis that places the first and second hollow bodies 134, 136 in communication. If the hollow bodies 134, 136 are blood (or other fluid) carrying structures, the anastomosis places them in fluid communication and provides a fluid-tight seal.--

Please replace the paragraph beginning on page 14, line 9 with the following corrected paragraph:

--The embodiment of Fig. 13 uses first and second securing components 142, 144 which are respectively positioned adjacent openings in the hollow bodies 134, 136 so as to be partially disposed within the lumens thereof. The opening in each hollow body may be formed by making a surgical incision, removing tissue with a punch, etc. Each securing component 142, 144 includes a pair of members, and each member may comprise one or more materials and one or more layers. One member of each securing component 142, 144 is positioned within the lumen of its hollow body while the other member of the securing component is positioned on the exterior of the hollow body with tissue captured between the members of each component.--

Please replace the paragraph beginning on page 14, line 24 with the following corrected paragraph:

--Each securing component 150, 152 includes a single member that may be constructed as described above. An end of each hollow body 146, 148 is passed through the opening defined by a respective securing component and is then everted over the exterior of the component. As a result, joining the first and second securing components 150, 152 in end-to-end

fashion places the everted ends of the hollow bodies 146, 148 in sealed contact. In a case where the hollow bodies are natural blood vessels, such an anastomosis places the intimal surfaces of the vessels in contact.--

Please replace the paragraph beginning on page 16, line 3 with the following corrected paragraph:

--Figs. 19A-19C show a hollow body 180 which may, for example, represent a patient's coronary or peripheral artery, the lumen of which is stenosed at S. In Fig. 19A, the hollow body 180 is provided with the anastomotic securing component 170 of Figs. 18A-18B by coupling the securing component to an opening in the wall of the artery, thereby forming a site for creating an end-to-side or side-to-side anastomosis. In Fig. 19B, the hollow body 180 is provided with an alternatively configured anastomotic securing component 182 which includes a flange 184 and a discontinuous or segmented extension 186 passing all or partly through the opening in the wall of the hollow body. Fig. 19C shows a securing component 188 with a multi-part construction including a flange 190 and a separate extension 192 which is received in the opening of the hollow body 180. It should be understood that these are only a few of the various constructions that may be employed in practicing this aspect of the invention.--

IN THE CLAIMS:

Please cancel claims 2-45 without prejudice to their presentation in a later-filed patent application.

Please add the following new claims:

--46. A method for forming an anastomosis between first and second vessels using magnetic force, the method comprising steps of:

selecting a first vessel having a lumen;

selecting a second vessel having a lumen;

securing a first anastomotic component to the first vessel;

securing a second anastomotic component to the second vessel; and

using magnetic force to create an anastomosis between the first and second vessels with the first anastomotic component contacting the second anastomotic component.

47. The method of claim 46, wherein the first vessel is a coronary artery and the second vessel is a graft selected from the group consisting of natural blood vessels and vessels formed of synthetic material.

48. The method of claim 46, wherein the magnetic force is sufficient to maintain the anastomosis between the first and second vessels.

49. The method of claim 48, wherein only magnetic force is used to form the anastomosis between the first and second vessels.

50. The method of claim 46, further comprising the step of maintaining a full size of an opening in the first vessel.

51. The method of claim 46, wherein each of the first and second anastomotic components includes a material selected from the group consisting of magnetic, electromagnetic and ferromagnetic materials.

52. The method of claim 46, further comprising the step of preventing the first and second anastomotic components from moving toward each other beyond a predetermined distance.

53. The method of claim 46, wherein at least one of the first and second anastomotic components is secured to a respective vessel without penetrating the tissue of the vessel.

54. The method of claim 46, wherein at least one of the first and second anastomotic components is secured to a respective vessel without everting the vessel.

55. The method of claim 54, wherein the first and second anastomotic components are secured to the respective vessels without everting either vessel.

56. The method of claim 46, wherein the securing step is carried out with the first anastomotic component compressing the first vessel.

57. The method of claim 46, further comprising the step of forming a magnetic anastomosis between the second vessel and a third vessel so as to place the third vessel in communication with the first vessel.

58. The method of claim 57, wherein the first and second anastomotic components are separate and physically unconnected.

59. A method for forming an anastomosis between first and second vessels using magnetic force, the method comprising steps of:

selecting a first vessel having a lumen;

selecting a second vessel having a lumen;

securing a first anastomotic component to the first vessel;

securing a second anastomotic component to the second vessel; and

using magnetic force to create an anastomosis between the first and second vessels with the first anastomotic component contacting the second vessel.

60. The method of claim 59, wherein the first vessel is a coronary artery and the second vessel is a graft selected from the group consisting of natural blood vessels and vessels formed of synthetic material.

61. The method of claim 59, wherein the second vessel is a coronary artery and the first vessel is a graft selected from the group consisting of natural blood vessels and vessels formed of synthetic material.

62. The method of claim 59, wherein the magnetic force is sufficient to maintain the anastomosis between the first and second vessels.

63. The method of claim 62, wherein only magnetic force is used to form the anastomosis between the first and second vessels.

64. The method of claim 59, further comprising the step of maintaining a full size of an opening in the first vessel.

65. The method of claim 59, wherein each of the first and second anastomotic components includes a material selected from the group consisting of magnetic, electromagnetic and ferromagnetic materials.

66. The method of claim 59, further comprising the step of preventing the first and second anastomotic components from moving toward each other beyond a predetermined distance.

67. The method of claim 59, wherein at least one of the first and second anastomotic components is secured to a respective vessel without penetrating the tissue of the vessel.

68. The method of claim 59, wherein at least one of the first and second anastomotic components is secured to a respective vessel without everting the vessel.

69. The method of claim 68, wherein the first and second anastomotic components are secured to the respective vessels without everting either vessel.

70. The method of claim 59, further comprising the step of forming a magnetic anastomosis between the second vessel and a third vessel so as to place the third vessel in communication with the first vessel.

71. The method of claim 70, wherein the first and second anastomotic components are separate and physically unconnected..--

REMARKS

By way of this Preliminary Amendment, Applicant has cancelled originally-filed claims 2-45 without prejudice and added new claims 46-71. Claims 1 and 46-71 therefore are now pending in this application. Attached is a marked-up version of the changes made to the specification by the current amendments (captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE").

Applicant submits the present amendments prior to examination and as such, it should be appreciated that the cancellation and addition of claims is neither intended nor designed to distinguish the prior art. Applicant respectfully requests favorable action on the merits with respect to newly-added claims 46-71.

If the Examiner wishes to discuss any aspects of the present application, she is invited to telephone the undersigned at (650) 685-9205. Please charge any required fees, including any necessary extension-of-time fees, or credit any overpayment to Deposit Account No. 50-1247.

Respectfully submitted,

Date March 4, 2002

Michael J. Lynch, Reg. No. 36,403

HOEKENDIJK & LYNCH, LLP
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(650) 685-9205

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The following has been added after the title:

-- CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of application Serial No. 09/562,599, filed April 29, 2000. The complete disclosure of the aforementioned related U.S. patent application is hereby incorporated herein by reference for all purposes.--

The first paragraph has been amended as follows:

The invention relates to methods and devices for forming an anastomosis between two hollow bodies, and more particularly to forming an anastomosis using magnetic force.

The first paragraph on page 3 has been amended as follows:

According to one embodiment, the invention provides a method using magnetism for forming an anastomosis between first and second hollow bodies. Each hollow body has a lumen and an opening extending into the lumen. The method is carried out by positioning a first securing component adjacent the opening in the first hollow body, positioning a second securing component adjacent the opening in the second hollow body, and using magnetic force to form an anastomosis between the first and second hollow bodies with the lumens of the first and second hollow bodies in communication.

The paragraph beginning on page 3, line 10 has been amended as follows:

According to another embodiment, the invention provides a method using magnetism for forming an anastomosis between first and second hollow bodies, each of which has a lumen. The method uses magnetic force to form an anastomosis between first and second hollow bodies so as to place their lumens in communication. The first hollow body has proximal and distal portions between which the anastomosis is disposed.

The paragraph beginning on page 3, line 15 has been amended as follows:

According to another embodiment, the invention provides a method using magnetism for forming an anastomosis between first and second hollow bodies with lumens and openings extending into the lumens. This method is performed by positioning a first securing component adjacent an opening in the first hollow body, positioning a second securing component adjacent an opening in the second hollow body, and using magnetic force to form an anastomosis between the first and second hollow bodies with the lumens of the first and second hollow structures in communication. At least one of the securing components is positioned without everting the hollow body.

The paragraph beginning on page 3, line 23 has been amended as follows:

According to still another embodiment, the invention provides a method using magnetism for forming an anastomosis between first and second hollow bodies by positioning a first securing component adjacent the first hollow body, positioning a second securing component adjacent the second hollow body, and using magnetic force to control the relative position of the first and second securing components and to form an anastomosis between the first and second hollow bodies. The blood-carrying lumens of the first and second hollow bodies are placed in communication, with at least one of the first and second securing components at least partially disposed within the blood-carrying lumen of one of the first and second hollow bodies.

The paragraph beginning on page 4, line 11 has been amended as follows:

According to yet another embodiment, the invention provides a system for forming an anastomosis between first and second hollow bodies in a patient's body. The system includes first and second securing components capable of producing a magnetic field that applies force to maintain the securing components in a desired relative position. The first securing component has an opening and is substantially plate-shaped and sized and configured to be at least partially received in a lumen of a hollow body in a patient's body, and the second component has an opening and is sized and configured to be positioned adjacent a second hollow body in the patient's body for forming an anastomosis between the first and second hollow bodies.

The paragraph beginning on page 4, line 24 has been amended as follows:

Fig. 6 is a perspective view showing two hollow bodies adapted to be joined in communication [ ]via an end-to-side anastomosis;

The paragraph beginning on page 4, line 26 has been amended as follows:

Fig. 7 is a perspective view showing two hollow bodies adapted to be joined in communication [ ]via a side-to-side anastomosis;

The paragraph beginning on page 4, line 28 has been amended as follows:

Fig. 8 is a perspective view showing two hollow bodies adapted to be joined in communication [ ]via an end-to-end anastomosis;

The paragraph beginning on page 5, line 4 has been amended as follows:

Fig. 9A is a sectional view **[taken along line A-A]** <u>of the anastomosis shown</u> in Fig. 9;

The paragraph beginning on page 6, line 10 has been amended as follows:

Fig. 18B is a longitudinal sectional view of the hollow body and securing component shown in Fig**[s]**. 18A;

The heading on page 7, line 14 has been amended as follows:

DETAILED DESCRIPTION OF **[THE DRAWING FIGURES]** <u>PREFERRED EMBODIMENTS</u>

The paragraph beginning on page 7, line 15 has been amended as follows:

The present invention relates to methods and devices for forming an anastomosis between first and second (or additional) hollow bodies located in a patient's body, for example, a connection between a graft vessel and coronary or peripheral blood vessels, viscera, reproductive ducts, etc. The anastomosis places the hollow bodies, more specifically the lumens of the hollow bodies, in communication[ ]. In the case of blood-carrying bodies (or other hollow bodies that

carry fluid) the anastomosis places the bodies in fluid communication. The hollow bodies being joined may comprise native or autologous vessels, vessels formed of synthetic material such as ePTFE, DACRON®, etc.

The paragraph beginning on page 8, line 3 has been amended as follows:

Fig. 2 shows an elliptical-shaped, anastomotic securing component 14 with an opening 16. The securing component 14 is generally plate-shaped and the opening 16 is configured to provide the securing component 14 with larger end portions 18 than side portions 20. Fig. 3 shows a racetrack-shaped securing component 22 with an opening 24. As in securing component 14, the opening 24 provides securing component 22 with larger end portions 26 than side portions 28. Fig. 4 shows a securing component 30 with an opening 32, two end portions 34, 36 and two side portions 38. The securing component 30 has a generally racetrack-shaped configuration, however, the end portion 36 is larger than the end portion 34 which provides the component 30 with an asymmetric configuration. Stated otherwise, the opening 32 is not centrally located with respect to the body of the component 30, unlike the openings 12, 16 and 24 of respective securing components 10, 14 and 22 shown in Figs. 1-3. Also, the end 36 provides a tapered leading edge for easier introduction into a hollow body such as <u>a</u> blood vessel.

The paragraph beginning on page 9, line 6 has been amended as follows:

According to preferred embodiments of the invention the anastomotic securing components are formed of or have incorporated therein a material capable of producing a magnetic field that acts to maintain the components in a desired positional relationship. The magnetic field results in the securing components maintaining the first and second hollow bodies in a desired position so as to be in fluid-tight communication[ ]. The material used to form one or both securing components is preferably magnetic, ferromagnetic or electromagnetic.

The paragraph beginning on page 9, line 27 has been amended as follows:

Suitable materials that may be used to form an anastomotic securing component that is capable of producing a magnetic field include NdFeB (Neodymium Iron Boron), SmCo (Samarium Cobalt), and Alnico (Aluminum Nickel Cobalt). NdFeB is currently preferred for**[ce]** its force characteristics. The amount of force **[exerts]** <u>exerted</u> will depend on various

factors including the materials used, the size of the magnets and the number of magnets. In addition, different applications will call for different force ranges. For instance, it may be desirable to minimize the force as much as possible while still achieving a fluid-tight and secure attachment when treating small diameter blood vessels. As an example, in anastomosing coronary vessels, it is preferred to use anastomotic securing components that produce magnetic force in the area of less than 0.25 lbs, and more preferably approximately 0.15 lbs or less.

The paragraph beginning on page 10, line 7 has been amended as follows:

Figs. 6-8 depict first and second hollow bodies that have been prepared for anastomosis in three different manners. Fig. 6 shows a first hollow body 50 with an opening 52 that is adapted to be joined to an opening 54 of a second hollow body 56 to form an end-to-side anastomosis. The completed anastomosis places the lumens of the respective hollow bodies in communication[ ]. The opening 52 is formed in the wall of the first hollow body 50, for example, by incising or punching the tissue of the wall, while the opening 54 is defined by an end of the second hollow body 56. Fig. 7 shows a first hollow body 58 with an opening 60 adapted to be joined to an opening 62 of a second hollow body 64, thereby forming a side-to-side anastomosis that places their lumens in communication . The openings 60, 62 are formed in the walls of the hollow bodies 58, 64, for example, as described above regarding opening 52. Fig. 8 shows a first hollow body 66 with an opening 68 adapted to be joined to an opening 70 of a second hollow body 72 to form an **[end-to-side]** <u>end-to-end</u> anastomosis. Each opening 68, 70 is defined by an end <u>of</u> its associated hollow body 66, 72.

The paragraph beginning on page 11, line 9 has been amended as follows:

One exemplary application of this particular feature of the invention comprises a securing component with a middle layer of NdFeB (Neodymium Iron Boron -- magnetic) and two outer layers of 302 stainless steel (non-magnetic). The outer layers are bonded by suitable adhesive to the middle layer. Alternatively, the two outer layers could comprise a magnetic material, e.g., 440C stainless steel, surrounding a middle layer that is either magnetic or non-magnetic. As an example, the securing component may comprise a 0.008[”] <u>inch</u> thick magnetic layer and two 0.001[”] <u>inch</u> outer steel layers. It will be understood that this aspect of the invention may be practiced using other materials.

The paragraph beginning on page 11, line 17 has been amended as follows:

A benefit of this construction is that it allows the thickness of the magnetic layer to be reduced (which makes the brittle magnet more easily fractured) because the other layer(s) may be formed of a material which provide the assembly with the necessary strength, even if the other layer is very thin. In the above example, the steel layers may be very thin yet still able to absorb the load, e.g., the tensile forces that arise during movement of the hollow body or adjacent tissue. The particular overall dimensions of the securing component, as well as the dimensions of individual layer (or layers if a multilayer construction is used) will of course depend on the application. (As examples, for the securing component 22 shown in Fig. 3, the thickness in inches is preferably less than 0.040["], and more preferably less than 0.020["], e.g., approximately 0.015["] or even less, e.g., 0.008["].)

The paragraph beginning on page 12, line 27 has been amended as follows:

Fig. 10D shows an embodiment of the invention similar to that of Fig. 10C with first and second securing components 112, 114 coupled to first and second hollow bodies 116, 118. The means for attaching the first securing component 112 to the first hollow body 116 in this embodiment comprises an expandable member 120, such as a stent, disposed within the lumen of the first hollow body. The member 120 forces the end of the first hollow body 116 against the first securing component 112 to attach the elements in a fluid-tight fashion. It will be appreciated that the embodiments of Figs. 10C and 10D are only two of the various ways in which a securing component may be coupled to a hollow body without everting tissue of the hollow body.

The paragraph beginning on page 13, line 26 has been amended as follows:

Figs. 12 and **[13]** 14A-14B show other embodiments of the invention wherein first and second hollow bodies 134, 136 are respectively provided with securing components in order to create **[an end-to-side]** a side-to-side anastomosis. The embodiment of Fig. 12 utilizes first and second securing components 138, 140 respectively positioned adjacent openings in the hollow bodies 134, 136. Each securing component 134, 136 includes a single member that may

comprise one or more materials and one or more layers, as described above. The components may be fixed by adhesive or other means or remain in position via magnetic force, as explained above. The securing components 138, 140 are positioned through openings formed in the wall of the hollow bodies 134, 136 and are located within the respective lumens L1, L2 thereof, as shown in Figs. 14A and 14B. Once joined, the components 138, 140 form a fluid-tight anastomosis that places the first and second hollow bodies 134, 136 in communication[ ]. If the hollow bodies 134, 136 are blood (or other fluid) carrying structures, the anastomosis places them in fluid communication and provides a fluid-tight seal.

The paragraph beginning on page 14, line 9 has been amended as follows:

The embodiment of Fig. 13 uses first and second securing components 142, 144 which are respectively positioned adjacent openings in the hollow bodies 134, 136 so as to be partially disposed within the lumens thereof. The opening in each hollow body may be formed by making a surgical incision, removing tissue with a punch, etc. Each securing component 142, 144 includes a pair of members, and each member may comprise one or more materials and one or more layers. One member of each securing component 142, 144 is positioned within the lumen of its hollow body while the other member of the securing component is positioned on the exterior of the hollow body with tissue **[in between]** captured between the members of each component.

The paragraph beginning on page 14, line 24 has been amended as follows:

Each securing component 150, 152 includes a single member that may be constructed as described above. An end of each hollow body 146, 148 is passed through the opening defined **[in]** by a respective securing component and is then **[is]** everted over the exterior of the component. As a result, joining the first and second securing components 150, 152 in end-to-end fashion places the everted ends of the hollow bodies 146, 148 in sealed contact. In a case where the hollow bodies are natural blood vessels, such an anastomosis places the intimal surfaces of the vessels in contact.

The paragraph beginning on page 16, line 3 has been amended as follows:

Figs. 19A-19C show a hollow body 180 which may, for example, represent a patient's coronary or peripheral artery, the lumen of which is stenosed at S. In Fig. 19A, the hollow body 180 is provided with the anastomotic securing component 170 of Figs. 18A-18B by coupling the securing component to an opening in the wall of the artery, thereby forming a site for creating an end-to-side or side-to-side anastomosis. In Fig. 19B, the hollow body 180 is provided with an alternatively configured anastomotic securing component 182 which includes a flange 184 and a discontinuous or segmented extension 186 passing all or partly through the opening in the wall of the hollow body. Fig. 19C shows a securing component 188 with a multi-part construction including a flange 190 and a separate extension 192 which is received in the opening of the hollow body 180. It should be understood that these are only a few of the various constructions that may be employed in practicing this aspect of the invention.